

March 11, 1999

**Supplement to the Environmental Assessment for FAP 9A4648**

*This document incorporates by reference the petitioner's environmental assessment (EA) dated February 12, 1999.*

In the EA, the petitioner addresses the potential introduction of substances into the environment as a result of the discharge of wastewater from food-processing facilities. The petitioner discusses the fact that these facilities will need to obtain appropriate permits and approvals in order to discharge process waters to publicly owned treatment works (POTWs). We note that food-processing facilities that directly discharge process waters into surface waters must also obtain the appropriate permits and approvals. The use and discharge of an antimicrobial agent at point sources in the United States are subject to the requirements of National Pollution Discharge Elimination System (NPDES) permits under the Clean Water Act (33 U.S.C. 1251 et seq.). Users of the antimicrobial agent must not 1) discharge the product into lakes, streams, ponds, estuaries, oceans, or other waters unless the discharge is in accordance with the requirements of an NPDES permit and the user has notified the permitting authority in writing prior to discharge, and 2) discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority.



Jeanette Glover Glew

99K-0299

EA-2

# Alcide CORPORATION

8561 154th Avenue NE, Redmond, WA 98052 425-882-2555 Fax: 425-861-0173



1999 FEB 16 P 3: 17

Dr. R.L. Martin,  
Food and Drug Administration,  
Center for Food Safety & Applied Nutrition,  
200 C St., SW,  
Washington,  
DC, 20204-0001.

February 12, 1999

Fax: [1] 202-418-3131

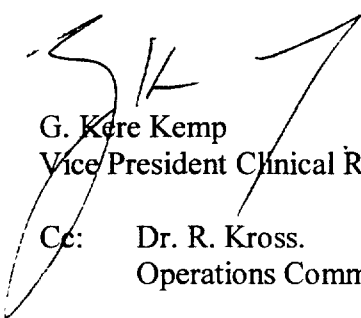
Dear Dr. Martin:

Re: Food Additive Petition 9A4648

In response to our telephone discussions of earlier this week, enclosed please find a revised Section 171.1(c)(H) Environmental Assessment (five copies) for the above numbered petition. This section has been amended to remove all references to the use of acidified sodium chlorite for any purpose other than on raw agricultural commodities post-harvest. For ease of handling, this revised section has been foot marked with today's date and paginated from page 0001.

Please contact me if you require any additional comment

Yours sincerely,



G. Kere Kemp  
Vice President Clinical Research

Cc: Dr. R. Kross.  
Operations Committee.

File: 750(b)

002114



## **§171.1(c)(H) ENVIRONMENTAL ASSESSMENT**

### **Section Contents.**

- 1.0. DATE. February 12, 1999**
- 2.0. PETITIONER. Alcide Corporation**
- 3.0. ADDRESS. 8561 154th Avenue, NE  
Redmond, WA 98052.**
- 4.0. DESCRIPTION OF THE PROPOSED ACTION.**
- 5.0. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE  
SUBJECT OF THE PROPOSED ACTION.**
- 6.0. INTRODUCTION OF SUBSTANCES INTO THE  
ENVIRONMENT.**
- 7.0. FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT.**
- 8.0. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES.**
- 9.0. USE OF RESOURCES AND ENERGY.**

**002115**

**10.0. MITIGATION MEASURES.**

**11.0. ALTERNATIVES TO PROPOSED ACTION.**

**12.0. PREPARER.**

**13.0. CERTIFICATION.**

**14.0. APPENDICES.**

**15.0. BIBLIOGRAPHY.**

## **4.0. DESCRIPTION OF THE PROPOSED ACTION.**

### **4.1. REQUESTED APPROVAL.**

Approval is requested for the use of acidified sodium chlorite (ASC) solutions as post-harvest treatments of fresh produce in order to reduce the numbers of pathogenic and spoilage microorganisms on their surfaces. There are two components used to create these solutions, the sodium chlorite and those GRAS acids which do not create undue levels of chlorine dioxide upon combination with the chlorite. The acidified chlorite solutions may be produced and used, primarily as a spray, at one or several stages of the processing operation: a) directly after harvesting; b) after washing with water, if performed; c) and after cutting, paring, peeling, or segmenting, if performed. The liquid is generally applied from a sprayer, at an effective pressure range, in which either i) two streams of the chlorite and the acid solutions are mixed at, or immediately before the spray nozzle, or ii) a single stream of acidified chlorite is directed to the spray nozzle from a pre-mixed solution. The latter may be prepared up to 8-hours prior to spraying, preferably in cold water, with the chlorite and acid levels having been analytically determined to be within approved levels. If the produce is to be immersed, the liquid may similarly be prepared up to 8-hours prior to immersion, with the chlorite and acid levels monitored and replenished as required by continuous use as a decontaminating solution. At this early stage, prior to actual commercial use of the product, it is considered premature to provide an estimation of the relative amounts of ASC solution that will be applied by spray vs. immersion, although economics would certainly favor the lower-volume usage afforded by spray application. In some commodities, where surface irregularities might minimize the effectiveness of spray applications, direct immersion would be indicated. A "guestimated" ratio of spray : immersion applications is ~90:10, although the volume usage would certainly be lower owing to the greater quantity of ASC required for immersion.

**002117**

It should be particularly noted, in this Environmental Assessment document, that technical grade lactic acid, although a GRAS material, is specifically excluded from this petition owing to the tendency of its impurities to trigger excessive levels of chlorine dioxide, of environmental concern, when combined with sodium chlorite.

#### **4.2. NEED FOR THE ACTION.**

Good hygienic practices following the harvesting of fruits and vegetables are necessary in order to ensure the microbiological safety and quality of the fresh produce. Millions of Americans suffer some sort of illness each year from something they eat. But Government officials indicate that less than 5 percent of food illnesses are ever reported to authorities, so they rely heavily on estimates. The Centers for Disease Control and Prevention estimates that *E. coli* O157:H7 infects up to 20,000 Americans a year through meat, produce and other sources. Of these up to 500 may die. This particular organism, of animal fecal origin, is present in manure and animal droppings which contaminate soil. Sewage sludge, when used for fertilization, certainly contributes additional problems. Since mid-1995, the C.D.C. has confirmed that more than 300 people had severe diarrhea and other illnesses in nine outbreaks of the *E. coli* strain derived from lettuce, alfalfa sprouts and fresh apple juice or cider.

There is ample evidence that fresh vegetables grown in polluted soil can be responsible for certain communicable diseases. Watercress, by nature of its growth and cultivation, is a good example of this contamination. Moreover, *Salmonella typhosa* has been known to live in the soil from 30 to 36 days, and in sterile sand for more than 60 days. Authorities believe that a small lettuce producer, operating under blatantly unsanitary conditions, was responsible for an outbreak of *E. coli* O157:H7 that sickened at least 61 people in Illinois, Connecticut and New York in May and June of 1996. Apparently the lettuce had been washed and packaged within 100 feet of a cattle pen, the probable source of fecal contamination. Infections have been reported from

other pathogens found in contaminated soil and water, such as pathogenic types of bacilli, *Streptococcus faecalis*, *Salmonella* species, and *Clostridium tetani*, although no firm statistics are available to quantify their numbers.

In one specific area of concern, premixed salads have become so popular that one trade group estimates that their sales reached \$1 billion nationally in 1997, from only \$82.6 million in 1989. Although some of these products are marked "certified organic," indicating that no pesticides or chemical fertilizers were used. Thus more "natural" fertilizers will tend to be used, and organic certification does not guarantee safe processing practices or the absence of harmful bacteria. In fact the FDA wants the food industry to take more responsibility in this area, and is developing voluntary guidelines to encourage safer handling and processing of fruits and vegetables, including hazard-control plans to ensure the destruction of contaminants.

Mechanical washing of produce, after harvesting, is perhaps the oldest method used to render the commodities more acceptable. However the primary purpose of this treatment continues to be a means to remove excess extraneous matter to gain an attractive appearance, not to reduce microbial contamination. There is no doubt that large numbers of organisms are removed by mechanical washing, but this method is not an effective means of rendering the product sterile, or even disinfected. Chlorinated water has been used in processing a variety of harvested produce, but by its nature its efficacy is dissipated by vegetable soil and organic matter.

Thus, while current techniques, both physical and chemical, have varying degrees of success in the reduction of pathogenic contaminants, there still is an acknowledged need for further means for ensuring the safety of the variety of the fresh produce which reaches the U.S. consumer's table. It is the position of the Alcide Corporation that the acidified sodium chlorite (ASC) solutions which are the subject of this Food Additive Petition, and which have already been approved by the FDA and

USDA for use in poultry processing, and by the FDA for red meat processing, can play a major role in upgrading the microbial quality of the fresh U.S. fruits and vegetables.

#### **4.3. LOCATIONS WHERE PRODUCTS WILL BE PRODUCED.**

There are two components to the acidified chlorite solutions being proposed for Secondary Direct Food Additive Status, the sodium chlorite and the acidifier to achieve the desired pH. The acidifier will be any one of a variety of FDA-approved GRAS acids, including phosphoric, sulfuric, malic, acetic and citric, but excluding any (such as technical-grade lactic) which may generate inappropriate levels of chlorine dioxide upon combination with chlorite. These GRAS acids are all materials of very high volume usage, and of many current diverse applications. The projected volumes of use as an activator of sodium chlorite are much below a fractional percentage of the other applications.

Sodium chlorite is currently being used as a  $\text{ClO}_2$  source in water treatment, as well as an industrial bleaching agent in a number of industries (primarily pulp and paper), in cleaning applications for the electronics industry, as a biocide in the food processing industry, and in various applications in the oil industry. On April 23, 1996 the U.S. FDA approved the use of sodium chlorite as a component of acidified sodium chlorite solutions, for pathogen reduction in poultry processing. They were thereafter approved such use in USDA-governed poultry facilities. Thereafter, on February 27, 1998, the FDA approved the use of ASC solutions in the processing of red meat carcasses.

The size of the North American market for sodium chlorite in 1992 was 18 million lb per year and, with the demand for chlorite growing (at the expense of chlorine) at a rate of 8% to 9% per year, it is expected that this market will exceed an estimated 25 million lb per year in 1998. The major production source has been the



Vulcan Chemicals facility in Wichita, Kansas. Sterling Chemicals, in Houston, has acquired Tenneco's production facility in Richmond, Virginia, to add to its 8 million lb per year sodium chlorite manufacturing plant in Buckingham, Quebec. Foreign production sites for sodium chlorite, which may be accessed if quality and economics are appropriate, include that of France's Atochem, S.A., the world's largest producer, and Energia Industrias Aragonesas, Madrid, Spain.

#### **4.4. LOCATIONS WHERE THE PRODUCTS WILL BE USED.**

Once the pending Food Additive Petition is accepted as a regulation, the acidified chlorite antimicrobial will become available to all growers and processors of fruits and vegetables for fresh use in the United States. Geographically these solutions should find application in all sections of the country where such produce is grown, although certain states are well recognized as primary sources of certain of these commodities. For example, California and Florida are major sources of citrus fruits (52% and 41%, resp.), and Washington, New York, Michigan and California account for most apple production (44%, 11%, 10% and 8%, resp.). States with colder climates, *e.g.* Montana, Utah, Idaho, Maine, generally produce less, but even Idaho and Maine are significant sources of potatoes. Thus there are no particular geographical areas in the United States where the ASC solutions will not have potential utility.

Total annual projected usage of ASC sprays throughout the United States, for fruit and vegetable disinfection, can be estimated on the basis of USDA<sup>1</sup> data for the 1992 and 1996 growing seasons, the latest for which such information is fully available. US production figures for each category were further subdivided into the percentage of total product for fresh use, as opposed to canning, freezing, drying, subdividing, etc. The usage is estimated to achieve 25% of the total potential fresh product market in the 10th year following approval.

**002121**

The produce, for convenience, can be subdivided into three categories [Fresh Market % of Total Production].

- Citrus Fruits [33.6%]
- Non-Citrus Fruits [38.2%]
- Vegetables [49.1%]

To obtain projected usage the following considerations were applied:

CITRUS FRUITS\*

- $8.36 \times 10^9$  pounds of fresh citrus fruits potentially treatable
- Average surface area of fruits =  $45 \text{ in}^2/\text{lb}$  [determined by averaging surface area/weight of various citrus fruits]
- Calculate from this that there are  $2.61 \times 10^9$  sq ft of sprayable surface annually, at 100% usage
- Using an estimated application rate of  $10 \text{ ml/sq ft}$  for the ASC solution yields  $2.61 \times 10^7$  liters of ASC solution sprayed
- At 1200 ppm sodium chlorite, this corresponds to  $6.9 \times 10^4$  lbs, or 34.5 tons of sodium chlorite.
- At 25% usage in 10 years, this would reach 8.6 tons of sodium chlorite that would be entering the environment annually, without degradation.
- \*- Oranges, Grapefruit, Lemons, Limes, Tangelos, Tangerines, Temples

NON- CITRUS FRUITS\*\*

- $1.3 \times 10^{10}$  pounds of fresh non-citrus fruits potentially treatable
- Average surface area of fruits =  $100 \text{ in}^2/\text{lb}$  [determined by averaging surface area/weight of a number of common fruits]
- Calculate from this that there are  $9.0 \times 10^9$  sq ft of sprayable surface annually, at 100% usage

- Using estimated application rate of 10 ml/sq ft for ASC yields  $9.0 \times 10^7$  liters of ASC solution sprayed
- At 1200 ppm sodium chlorite, this corresponds to  $2.38 \times 10^5$  lbs, or 119 tons of sodium chlorite
- At 25% usage in 10 years, this would reach 30 tons of sodium chlorite that would be entering the environment annually, without degradation.

#### NON-CITRUS FRUITS INCLUDED IN THE ABOVE

- \*\*\_- Apples, Apricots, Avocados, Bananas, Cherries, Cranberries, Dates, Figs, Grapes, Guavas, Kiwifruit, Nectarines, Olives, Papayas, Peaches, Pears, Pineapples, Plums, Prunes, Strawberries.

#### VEGETABLES\*\*\*

- $3.8 \times 10^{10}$  pounds of vegetables potentially treatable
- Average surface area of vegetables=  $78.7 \text{ in}^2/\text{lb}$  [determined by averaging surface area/weight of a number of common vegetables]
- Calculate from this that there are  $2.1 \times 10^{10}$  sq ft of sprayable surface annually, at 100% usage
- Using estimated application rate of 10 ml/sq ft for ASC yields  $2.1 \times 10^8$  liters of ASC solution sprayed
- At 1200 ppm sodium chlorite, this corresponds to  $2.52 \times 10^8$  gms, or  $5.55 \times 10^5$  lbs, or 277.5 tons of sodium chlorite
- At 25% usage in 10 years, this would reach 69 tons of sodium chlorite that would be entering the environment annually, without degradation.

\*\*\*- See following Table:

# VEGETABLE CANDIDATES FOR ASC SPRAY- FRESH USE; ANNUAL

Based on 1996 Crop Year

<u>C R O P</u>	<u>PRODUCTION (1000 TONS)</u>
Artichokes	20
Asparagus	50
Snap Beans	186
Beets	63
Broccoli	358
Brussel Sprouts	14
Cabbage	608
Carrots	1,352
Cauliflower	164
Celery	472
Corn	1,137
Cucumber	492
Eggplant	30
Escarole/Endive	28
Garlic	136
Lettuce, Head	3,293
" , Romaine	492
" , Leaf	467
Melons, Cantaloupe	1,106
" , Honeydew	267
" , Watermelons	2,206
Onions	3,078
Peas, Green	414
Peppers	413

**002124**

Spinach	98
Strawberries	407
Tomatoes	<u>1,543</u>
<i>TOTAL TONNAGE (x1000)</i>	<i>18,894</i>

These individual usage figures can now be combined into the total potential usage of sodium chlorite, from ASC treatments, in 10 years after approval of the present Food Additive Petition:

POTENTIAL ANNUAL CONSUMPTION OF SODIUM CHLORITE  
FROM USE AS DISINFECTING TREATMENT  
FOR FRUITS AND VEGETABLES\*

C R O P	TOTAL FRESH ANNUAL USE Lbs x 10 <sup>9</sup>	SPRAY VOLUME Liters x 10 <sup>7</sup>	SODIUM CHLORITE Tons
		--- at 25% use rate ---	
VEGETABLES	38	5.25	69
NON-CITRUS FRUITS	13	2.25	30
CITRUS FRUITS	8.4	0.65	8.6
<i>TOTAL - SODIUM CHLORITE USAGE</i>			<i>107.6 Tons</i>

\* When acidified sodium chlorite solution is used at maximum 1200 ppm concentration, at 25% of the maximum possible use rate after 10 years, on produce intended for fresh use. Application rate of 10 ml of solution per sq. ft. of surface.

002125

The total maximum projected use of sodium chlorite for agricultural commodities of 107.6 tons, 10 years after acceptance of ASC treatment, is 0.85% of total annual use of this material, based on current U.S. production.

**5.0. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE  
SUBJECT OF THE PROPOSED ACTION.**

**5.1. CHEMICAL NAMES AND PHYSICAL PROPERTIES.**

**5.1.1. Sodium Chlorite.**

CAS Reg. No.:	7758-19-2
Color (37% Solution):	Colorless to light green
Specific Gravity:	1.21
Viscosity (@25°C):	1.62 cps
pH:	12.33

**5.1.2. Acidifiers (GRAS). [REPRESENTATIVE]**

**Phosphoric Acid.**

CAS Reg. No.: 7664-38-2  
Conforms with 21CFR §182.1073 as a Multiple Purpose GRAS Food Substance

**Citric Acid.**

CAS Reg. No.: 77-92-9 (anhydrous)  
5949-29-1 (monohydrate)  
Conforms with 21CFR §182.1033 as a Multiple Purpose GRAS Food Substance

**Hydrochloric Acid.**

CAS Reg. No.: 7647-01-0  
Conforms with 21CFR §182.1057 as Multiple Purpose GRAS Food Substance

**002127**

**Malic Acid.**

CAS Reg. No.:	617-48-1	DL mixture
	97-67-6	L isomer

Conforms with 21CFR §184.1069 as a Specific Substance Affirmed as GRAS,  
with respect to the following ¶'s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

**Sulfuric Acid.**

CAS Reg. No.: 7664-93-9

Conforms with 21CFR §184.1095 as a Specific Substance Affirmed as GRAS,  
with respect to the following ¶'s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

**Acetic Acid.**

CAS Reg. No.: 64-19-7

Conforms with 21CFR §184.1005 as a Specific Substance Affirmed as GRAS,  
with respect to the following ¶'s,

- (a) description
- (b) specifications
- (c) use as a pH control agent
- (d) maximum use level

**002128**



The subject of this food additive petition (FAP) is the system comprised of acidified aqueous sodium chlorite solutions for use as an antimicrobial agent to reduce pathogenic microorganisms on fruits and vegetables for the fresh use market. The concentration of sodium chlorite in the ASC solutions will be from 500 to 1200 mg per liter (ppm), and the GRAS acid level will be such as to maintain the pH in the range of 2.3 to 3.2. The exact composition and concentrations of the components of the ASC solution for a particular use will depend on the mode and site of application of the antimicrobial solution.

## 5.2. MODE OF ACTION OF THE GERMICIDAL SYSTEM.

The germicidal activity of this antimicrobial system derives from the degradation of chlorous acid ( $\text{HClO}_2$ ) [CAS No. 13898-47-0] which will form as a predictable fraction of the total chlorite species ( $\text{ClO}_2^-$ ) in the solution. The degree to which chlorous acid forms will depend on the hydrogen ion concentration (i.e. pH) in the solution. Chlorous acid, an unstable material, can exist in equilibrium with the chlorite ion in aqueous systems with a stability proportional to its total concentration; the lower the concentration the slower the rate of degradation.

Chlorous acid has a  $\text{pK}_a$  of  $1.1 \times 10^{-2}$ , and from this constant the relative amount of chlorous acid can be calculated for the pH range of intended application of this acidified chlorite system. In the range of pH's, 2.3 - 2.9, the chlorous acid levels, as percentages of total chlorite ion, are as follows:

<u>pH</u>	<u>% Chlorite as <math>\text{HClO}_2</math></u>
2.3	32.0
2.4	27.0
2.5	22.2

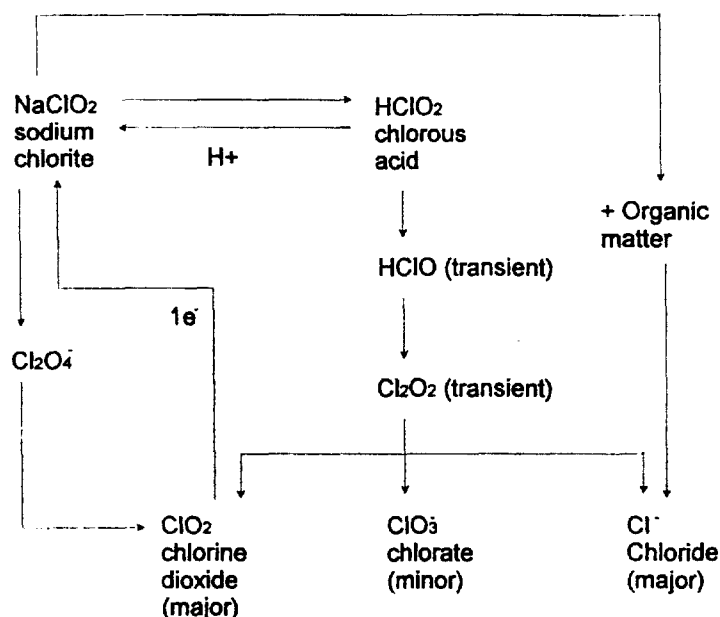
002129

2.6	18.1
2.7	15.0
2.8	12.3
2.9	10.0

To achieve these solution pH values, different quantities of the individual GRAS acids are required, depending on their strength. This can range from *ca.* 0.01% for a mineral acid to the *ca.* 1.5 - 2.5% level of acetic acid, the weakest that could be used for this purpose.

The ability to provide sustained antimicrobial activity based on the presence of chlorous acid relies on the presence of reservoirs of chlorite and hydrogen ions in the solution. As the chlorous acid is consumed, through interaction with microorganisms and certain other organic matter in solution, re-equilibration will occur to produce more of the chlorous acid. The following schematic covers the relevant aspects of this chemistry:

#### Schematic of Chlorite/Chlorous Acid System



002130

## **6.0. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT.**

### **6.1. PRODUCTION RELEASES.**

As noted above in Section 4, the acidified sodium chlorite solution will be produced on site where the produce will be treated. This will be i) directly after harvesting, ii) and/or after water washing, if performed; iii) and/or cutting, parting, peeling, or segmenting, if performed. Spray application is expected to be the primary mode of use of the ASC solutions. It will be accomplished using confluent streams of the acid activator and sodium chlorite solutions meeting and emerging at the nozzle. An alternate means the produce may be immersed in the mixed acid/chlorite treatment solution for a sufficient time to accomplish a significant reduction in microbial loading. In both cases the acid and sodium chlorite solutions, individually or mixed, will be prepared in cool tap water, so that during the brief time between creation and activation of the ASC solution the levels of free chlorine dioxide that are generated from the solution are not expected to exceed *ca.* 1 ppm (i.e. 1 mg/ liter).

The specific sites where the ASC solution will be applied will depend on circumstance and operational logistics. The treatment may be applied to the intact commodities in the field post-harvesting, as they move down a belt in a plant, intact or cut, or any combination thereof. The spray will generally be applied to the fruit or vegetable via pressurized spray nozzles, for a period of about 5 seconds, and then allowed to remain on the produce for about 30 seconds. Depending on the nature of the item, the fruit or vegetable may then be washed free of residual ASC material, or allowed to further degrade naturally in subsequent minutes.

In some applications, the spray treatment may take place in a semi-enclosed spray cabinet area, to reduce the potential for air levels to exceed the TLV's for chlorine

**002132**

As chlorous acid degrades it produces a series of transient oxidants, including hypochlorous acid and dichlorine dioxide; and ultimately chlorine dioxide ( $\text{ClO}_2$ ) [CAS No. 10049-04-4] if the intermediates are not consumed through a redox interaction with such organic materials as microorganisms. The  $\text{ClO}_2$  that forms may further combine with free chlorite ( $\text{ClO}_2^-$ ) to form the cidal oxidant  $\text{Cl}_2\text{O}_4^-$ .

The  $[\text{H}]^+$  ion source can be any protic acid which, for this application, must be a GRAS material that does not result in environmentally unsuitable levels of chlorine dioxide. Three such acids, covering a range of strengths, are phosphoric acid [CAS No. 7664-38-2], citric acid [CAS No. 77-92-9] and acetic acid [CAS No. 64-19-7].

**002131**

dioxide. The cabinet would be negatively pressurized via an aspirating air hose venting in a safe removed location. The liquid from the treatment will generally be diluted with other plant processing waters, where appropriate, where the unconsumed oxidants in the ASC solutions are expected to degrade through contact with soluble and suspended organic matter. The combined liquid waste would be routed to an normal plant disposal facilities, whether publicly-owned treatment works [POTW's], individual disposal systems, or into the soil. The latter, containing high levels of organic matter, should provide the most rapid reduction of the ASC oxidants. The technical literature, and Alcide's own laboratory studies, have consistently demonstrated the rapidity of oxychlorine depletion by reducible organic matter.

While chlorine dioxide has a minimum tendency to form when chlorite and suitable GRAS acids are initially combined immediately prior to spraying, it has an increasing tendency to form as the solution concentrates during the evaporative process. In a typical situation then, the potential for chlorine dioxide entry into the air of the workplace would derive from both that initially formed in solution (previously estimated as < 1.0 ppm), and any formed during evaporation. As indicated, chlorine dioxide has a significant tendency to react with, and be degraded by contact with oxidizable organic matter, such as the soil associated with harvested products. It is fully expected that a major portion of both the initially- projected chlorine dioxide maximum of 1 ppm in solution, and any quantity subsequently formed upon solution evaporation would be significantly converted back to chlorite, and possibly chlorate. It is further expected that the degree of evaporation of, and creation of chlorine dioxide from the ASC treatment during its brief residence on the commodity would be low. This is particularly true because the high humidity conditions prevailing in processing areas, which would tend to suppress evaporation. Thus the projected 1 mg/liter level of chlorine dioxide is expected to correspond to the maximum amount from both initial and evaporative sources.

**002133**

To put this into perspective, assume an ASC spray volume application of 8 oz. (ca. 240 ml) per 24 sq. ft. of produce surface, which is roughly represented by the following quantities of commodities:

- |                      |                     |                      |
|----------------------|---------------------|----------------------|
| - 100 Bananas-       | 150 Apples          | 275 Lemons/Kiwifruit |
| - 25 lbs of carrots  | - 90 lbs of onions  |                      |
| - 50 lbs of tomatoes | - 85 lbs of oranges |                      |

For each such volume of application, a 1 ppm maximum level of chlorine dioxide would be equivalent to 0.24 mg of chlorine dioxide present in the solution upon initial combination, or subsequent evaporation of the solution within about the next minute.

The water/air partition coefficient of chlorine dioxide at 15°C is 45<sup>2)</sup>, so 1/45th that amount, or 0.005 mg of chlorine dioxide would enter the surrounding air per treatment of the above quantities of produce. This quantity which would be generally removed by negative aspiration, such as from a confined cabinet or plastic-enclosed area in the which the ASC treatment were applied. The negative pressure applied to this enclosed area is expected to transfer the bulk of this gas to the drain effluent (along with any dissolved chlorine dioxide in the excess ASC solution), so that a projected maximum of 0.001 mg of chlorine dioxide per 8 oz of treatment solution would enter the air of the processing plant external to the semi-enclosed cabinet. This 0.001 mg would then be dispersed by the normal air dynamics of the processing plant.

If the ASC solution is applied to the fruits or vegetables by an immersion process, the potential for ClO<sub>2</sub> production is expected to be less than for the spray process. The lower ClO<sub>2</sub> would result from the fact that little or none would generate from the

**002134**

evaporation/concentration step that accompanies spray operation. Only that which slowly may form in solution, after initial combination of acid and the chlorite concentrates, would be present in the liquid; and much of it could be reduced by interaction with organic matter associated with the produce.

The OSHA TLV for chlorine dioxide is 0.3 mg/liter of air for continuous 8-hour exposure, which is 300X greater than the projected maximum of 0.001 mg per 8 oz. Based on these considerations, involving the maximum production of 1 ppm chlorine dioxide from the ASC treatment, neutralization of it by organic materials in the washings, and the venting to the immediate processing environment of a maximum of 0.001 mg per 8 oz of treatment, Alcide concludes that the air levels of chlorine dioxide in the processing plant, which results from the use of ASC disinfecting solutions is below concern. Random chlorine dioxide air analysis will be carried out in processing areas during early use of the ASC treatments, once approved, in order to verify these conclusions. Appropriate corrective measures will be taken, if necessary, to reduce any untoward levels.

## **6.2. USE RELEASES.**

The key areas of potential concern are listed as follows:

### **6.2.1. WATER AND AIR RELEASES.**

The components of the acidified chlorite/chlorous acid solution are the GRAS acid, of high purity, and the sodium chlorite (of a technical grade) which has sodium chloride and sodium chlorate as technical impurities. Upon acidification the chlorite, through chlorous acid, will slightly transform to chlorine dioxide and chlorate. At the level of use of these components, and the minimum standing time for the mixed ASC solution, the amount of chlorine dioxide will not exceed *ca.* 1 ppm. And, being a highly

**002135**

reactive compound, will be quickly reduced by reaction with organic matter, soil and microorganisms on the fruits or vegetables. The reduction will be to even smaller quantities of chlorite and chloride ions, with a lower amount of chlorate being formed by a disproportionation of the chlorine dioxide.

The air releases of chlorine dioxide, as shown in the previous Section 6.1 are considered to be negligible. Of greater possible concern is water releases, vis-à-vis the relatively higher levels of sodium chlorite, i.e. 1200 ppm as a maximum, of which the chlorite ion represents 895 ppm. The following projection puts this quantity into relative perspective, with respect to the total water throughput quantities in fruit and vegetable processing operations. No collection of data can be found on the quantities of water utilized in the diversity of water-washing operations where fresh-picked produce is first brought for cleaning and packaging. In many cases, as for tree-borne fruit or vegetables (*e.g.* apples, pears), little post-harvest washing may be employed. In other cases, such as for soil-contaminated vegetables (*e.g.* carrots, beets) ample water is required to eliminate extraneous matter.

A projected level of chlorite release into processing plant effluent water can be derived from specific information made available from a current processor of fresh vegetables. A single-day's run of 720,000 lbs of lettuce required 36,000 gallons of water for processing, in addition to other plant requirements for water such as transport of removed solids and overall plant sanitation. Calculations are confined, for the moment, to processing waters alone, and use the conservative estimate of 8 oz of ASC spray per 50 lbs of lettuce (based on the use rate for tomatoes, which have a lower surface-to-volume ratio). On that basis, 720,000 lbs of lettuce would consume  $[720,000/50] \times 8$  oz or 900 gallons of ASC spray. That would be diluted by 36,000 gallons of processing water, a 20-fold reduction. At a maximum use level of 1200 ppm (1.2 gms/liter) of sodium chlorite, the total sodium chlorite used per day would be about 9.0 lbs, containing

**002136**



about 6.7 lbs of chlorite. If none of the chlorite degraded as a result of the treatment or contact with organic matter (a conservative assumption) then that chlorite would be diluted into the 36,000 gallons of processing water. This would reduce the chlorite to about 22 ppm, assuming no degradation whatever of the chlorite *via* the chlorous acid route, or from oxidizable organics. This water is then diluted by the organic-laden effluent water used to transport soil and organic wastes, and the other waters utilized for plant processing. Assuming this total volume to be equal to that used for processing alone, the unreacted chlorite level would reduce to about 11 ppm. However, since the plant effluent, from all the sanitary and house-keeping operations, will contain considerable organic matter, a major fraction of the chlorite not already consumed will further degrade upon contact with this material. The fraction that might survive, on the basis of the known instability of chlorite in the ASC systems, and the high reactivity of the oxychlorines (chlorite, chlorate, chlorine dioxide) with soil and organic matter in general, is expected to be less than ~5% of initial quantities. So the water effluent from this processing facility, from the lettuce processing operation, would probably contain  $\leq 0.5$  ppm of chlorite. in the effluence water. Chlorate, present as an initial impurity in the chlorite, or formed during degradation, is anticipated to be <5% of that amount (*i.e.* <3 ppb). Facilities which process different vegetables or fruits, or have different water use rates will modify this quantity, but the survival of chlorite in all cases in plant effluent should still be in the low ppm or ppb range.

This effluent is then further directed ordinarily to external processing facilities, such as POTW's, where further dilution and degradation of the oxidants would take place (if any still survives).

The levels of acid used to achieve the requisite initial pH's of 2.3 - 2.9 for the ASC solutions, are as follows (for a few representative GRAS acids):

002137

Sulfuric acid-	<0.04% (<400 ppm)
Phosphoric acid-	0.02 - 0.04% (200 - 400 ppm)
Malic acid-	0.04 - 0.08% (400 - 800 ppm)
Acetic acid-	0.50 - 1.0% (5000 - 10,000 ppm)

These levels are reduced by their subsequent dilution in the quantities of water used for washing and plant sanitation, and are therefore of little environmental concern.

#### **6.2.2. RELATION OF PLANT WATER RELEASES TO TOTAL POTW QUANTITIES.**

The contribution of industrial discharges, such as from produce processing plants, to Publicly Owned Treatment Works (POTWs) is further diluted by discharges from non-industrial sources. An approximation of the further dilution by these other sources can be made from information that is available in an EPA-sponsored study by Consulting Engineers<sup>3</sup> of discharge sources which have a negative impact on the operation of POTWs. The POTWs studied included a representative cross-section of U.S. municipal treatment facilities serving industrial and non-commercial dischargers. In the 29 Case Study Reports provided in the survey, 26.3% of the influent waste water to these facilities derived from industrial sources.

A single industrial discharge source to a particular POTW, such as a fruit or vegetable processing facility, can be conservatively estimated to represent an upper limit of 50% of the total industrial discharge to a single POTW. Thus a water flow percentage contributed by a single processor to a POTW is 26.3% x 50%, or 13.2% of the total water processed. On that basis, the maximum combined oxychlorine levels which enter an average POTW, from the plant discussed above, would be  $<0.5\text{ppm} \times 13.2\% = 66\text{ ppb}$  assuming the highly unlikely situation that the various oxychlorines would not have been

**002138**

all fully reduced to chloride ion by oxidizable matter in the industrial discharges.

For the various food grade acids mentioned above, the only one of possible concern would be phosphoric acid, where the maximum 400 ppm applied would be diluted to about 40 ppm in the effluent, and then to 5 ppm by application of the 50% and 26.3% reduction factors described above. Since the dilution factors will be quite variable from location to location, those processors with phosphate discharges that might potentially impact their current NPDES permit, must of needs monitor their phosphate effluents, or simply make use of an alternate GRAS acid to activate the ACS system.

Alcide Corporation does not believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of POTWs, for the following reasons:

- a) The levels of oxychlorines, including chlorite, chlorate, and chlorine dioxide, that would reach the POTW's, is at the ppb level, at most. Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in POTWs, as provided in Appendix A (Page 125) of the Wetzel document. These interfering substances, as contained in certain industrial discharges, can cause "a POTW's noncompliance with its permit or inability to lawfully use or dispose of its sludge." Chloride was listed as a potentially interfering substance, but at a level significantly higher (180 ppm) than its presence either as an impurity in the technical grade chlorite or if all the oxychlorines were converted to chloride. Acidity is also listed as a potential interference in POTW operation, but the levels contributed by this application would not have a measurable impact on pH.

**002139**

- b) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the calculated ppb level; neither will the chlorite, a much weaker source of activity, at the minuscule levels possibly present.
- c) "Most interference problems at POTWs are related to intermittent discharges of high-strength conventional wastes which overload a POTW's organic capacity, causing plant upset," according to an EPA report<sup>4</sup>. Organic contributions and other common plant interference are not significant factors here:

low pH . . . . .[corrosion]  
solids or viscous pollutants . . . [flow obstruction]  
high volatiles . . . . [explosion or fire hazard]  
heated discharges . . . [altered biological activity]  
toxic discharges . . . .[inhibited biological  
activity]

### 6.2.3. COMPLIANCE WITH EMISSION REQUIREMENTS.

Alcide is not aware of any federal, state or local water or air emission regulations applicable to chlorite, chlorate or chlorine dioxide. Alcide fully anticipates that any fresh fruit or vegetable processor who intends to use the acidified sodium chlorite/chlorous acid solutions will obtain appropriate permits and approvals for discharging process waters containing chlorite, chlorate, chlorine dioxide, or possibly phosphates to POTWs. It should be noted that sodium chlorite, used in preparation of these ASC solutions, is an EPA-registered product. It is Alcide's current intention to use one of three EPA registered

002140

sodium chlorite products for the proposed application (or the equivalent): Vulcan Chemicals' 79% Technical Sodium Chlorite, Technical Sodium Chlorite Solution 31.25, and 31% Active Sodium Chlorite Solution. Copies of the Technical Data Sheets and Material Safety Data Sheets for these products are provided in Appendix I of this section.

Alcide intends to request that Vulcan Chemicals include label copy which mandates that users of the sodium chlorite must discharge the solutions in accordance with the requirements of the facility's National Pollution Discharge Elimination System permit.

Any warning statements on the labels concerning the hazard of the products to organisms that may be exposed to it in the environment will also be on the labels of the FDA-regulated use.

Alcide has carried out a number of experimental trials on the use of ASC solutions for reducing microbial levels on fresh fruits, fruit segments and a variety of vegetables, on the basis of which it does not anticipate any compliance problems resulting from the use of these solutions in the processing of these commodities. The Company therefore considers that no extraordinary circumstances will occur that might lead to non-compliance with emission requirements.

#### **6.2.4. COMPLIANCE STATUS.**

Sodium chlorite has a number of commercial uses, primarily as a source of chlorine dioxide, e.g. pulp and paper bleaching, drinking water treatment, as a slimicide in cooling towers, as a food disinfectant, and as a cleaning agent in the electronics industry. The current U.S. production of sodium chlorite is close to 25 million pounds. If as many as 25% of the processors of fruits and vegetables for the fresh market make use of the ASC system, 10 years after approval of this Food Additive Petition, the resulting anticipated usage of 107.6 tons of sodium chlorite would correspond to only 0.85% of that currently employed. Even with the recent FDA- and USDA-approval of

**002141**

ASC solutions for poultry processing waters, the combined level is not expected to exceed about 1% of current usage, under optimistic use projections. Accordingly, Alcide does not believe that approval for the proposed use will affect current compliance by sodium chlorite producers with environmental regulations.

Use of the food grade acid activators is significantly less, of a larger total commercial utilization, and a similar conclusion is drawn for these materials as well.

**002142**

## **7.0. FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT.**

Sodium chlorite, sodium chlorate and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, and/or microbial degradation wherein microorganisms can use the oxychlorines as an oxygen source when present at sublethal levels. Ultimately the oxychlorines will be reduced to the chloride ion,  $\text{Cl}^-$ . Full support for this conclusion is embodied in earlier §'s 5.2 (Mode of Action of the Germicidal System), 6.1 (Production Releases), and 6.2 (Use Releases).

**002143**

## 8.0. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES.

### 8.1. EFFECTS ON AQUATIC ORGANISMS.

A variety of studies that have been carried out on the acute toxicity of technical grade sodium chlorite and sodium chlorate to both freshwater and marine species form the base set of data which the U.S. EPA uses for evaluation purposes. Apparently, no such data set is available on chlorine dioxide. For the latter material, the rapidity of degradation by organic matter and the resulting minimal releases on production eliminate aquatic toxicity of  $\text{ClO}_2$  releases from consideration.

Reference is made to the aquatic toxicity data provided in FAP 4A4408, format item 8 of the revised Environmental Assessment, dated September 15, 1994. The data, reproduced in the following table show that, for sodium chlorate, the  $\text{LC}_{50}$  for 48-96 hour exposure for freshwater and marine fish, the Eastern oyster, shrimp and *Daphnia magna* is consistently  $>1000$  ppm. Sodium chlorate, then, is of no concern since anticipated releases of chlorate, from use of ASC solutions in processing of the fresh produce are approximated at  $<250$  ppb. The  $\text{LC}_{50}$  aquatic toxicity of sodium chlorite to fish and oyster species ranged from 41 to 129 ppm, above the maximum projected 0.5 ppm (500 ppb) POTW influx for chlorite. The 161 ppb 48 hr  $\text{LC}_{50}$ 's for *Daphnia magna* appears potentially problematic, but it is fully anticipated that chlorite ion will not survive contact with organic effluents to approximate such levels. Plant effluents during early applications of this technology will accordingly be monitored for chlorite levels to determine if the conservatively-estimated amounts of this species will actually occur. If so, measures will be taken to neutralize these oxidants in discharge waters. It should be noted that the U.S. EPA has determined that sodium chlorite is toxic to fish, based on its toxicity to *Daphnia magna*.

002144



<u>Test</u>	<u>Sodium Chlorite</u>	<u>Sodium Chlorate</u>
Bluegill Sunfish	100 ppm (96 hr LC <sub>50</sub> )	> 1000 ppm (96 hr LC <sub>50</sub> )
Rainbow Trout	41 ppm (96 hr LC <sub>50</sub> )	> 1000 ppm (96 hr LC <sub>50</sub> )
<i>Daphnia magna</i>	161 ppb (48 hr LC <sub>50</sub> )	> 1000 ppm (48 hr LC <sub>50</sub> )
Mysid Shrimp	650 ppb (96 hr LC <sub>50</sub> )	> 1000 ppm (96 hr LC <sub>50</sub> )
LC <sub>50</sub> )Eastern Oyster	129 ppm (96 hr LC <sub>50</sub> )	> 1000 ppm (96 hr LC <sub>50</sub> )
Sheepshead Minnow	105 ppm (96 hr LC <sub>50</sub> )	> 1000 ppm (96 hr LC <sub>50</sub> )

## 8.2. EFFECTS ON TERRESTRIAL ORGANISMS.

A broad variety of toxicological studies have been carried out on the oxychlorine species chlorite, chlorate and chlorine dioxide, in connection with the worldwide use of chlorine dioxide in the disinfection of potable water. The ClO<sub>2</sub> has been found to produce virtually no chlorinated hydrocarbons as potential mutagens, as does chlorine. On a concentrated basis, the oxychlorines have been found to cause oxidative changes to erythrocytes, both in loss of structural integrity and formation of methemoglobin. However at the low concentration levels where these materials may be found in produce processing plant effluents, the data obtained in connection with drinking water levels of the oxychlorines are more relevant.

On an acute basis, the following is a summation of exposure to high levels of dissolved chlorite and chlorate.

**002145**

**LD<sub>50</sub> Values for Chlorite and Chlorate in Mammals\***

SPECIES	ROUTE		CHLORITE	CHLORATE
	ORAL	I.P.	- - - mg/kg - - -	
Mouse	X		350	
		X		596
Rat	X		350	1200
Dog	X			700
Cat	X			1350
Guinea Pig	X		300	
Rabbit	X			8000

\*-Source of data; TOXNET

With respect to the acute toxicity of chlorine dioxide, an LD<sub>10</sub> of 500 ppm was found for 15 minutes air exposure by rats. In man, a 5 ppm level in the air was found to be an irritant to the respiratory and G.I. tracts. Such levels would not be found in fruit and vegetable processing plants, where any sub-ppm levels of ClO<sub>2</sub> formed during production of the ASC solutions would be rapidly destroyed by organic matter associated with the produce. With respect to ingestion at subacute levels, Bianchine, *et al.*<sup>5</sup> report on two adults who ingested 250 ml of chlorine dioxide in water containing a concentration of 40 mg/L (~ 0.142 mg/kg for 70 kg person). Within 5 minutes of ingestion, sudden headache, nausea, abdominal discomfort and lightheadedness occurred, which disappeared after 5 minutes. For sodium chlorite ingestion at subacute levels, Lubbers, *et al.*<sup>6</sup> gave 10 male volunteers sodium chlorite in drinking water in two separate phases. In the first phase, subjects drank 1 liter of chlorite-containing water for 6 days, with 2 days intervening between each exposure day. The first day, the concentration of sodium chlorite was 0.01

between each exposure day. The first day, the concentration of sodium chlorite was 0.01 mg/L, and this was increased each exposure day to a final concentration of 2.4 mg/L (0.034 mg/kg/day). Group mean values were determined for 2 days following each exposure for all investigated effects, including many serum chemistries and blood-cell counts as well as ECG analysis and physical examinations. All parameters measured were within normal ranges, and no trends or interactions judged to be of clinical significance were found. In the second phase, 10 volunteers drank 500 ml of water containing 5mg/L sodium chlorite daily for 12 weeks (average 0.034 mg/kg/day). Significant ( $p<0.05$ ) group-time interaction was found in the case of group mean corpuscular hemoglobin; however linear regression analysis did not show a significant trend, and the physiological significance of this interaction was doubted. Similar controlled clinical investigations were conducted on human volunteers ingesting chlorite or chlorate<sup>7,8,9</sup>, and similar results were obtained from subsequent statistical evaluation of the data.

A recently completed rodent 90-day study, considered to be the "most definitive and comprehensive study of chlorite undertaken" and ...considered...the most relevant basis for risk assessment"<sup>10</sup> was used, in conjunction with the earlier studies to calculate a NOEL (no observed effect level) for chlorite in drinking water of 5/mg/kg/day. This corresponds to 350 mg/kg/day intake for a 70 kg individual. Applying a 100-fold safety factor, this reduces to a recommended maximum intake of 3.5 mg/day for that individual. In the same publication a NOEL for chlorate is recommended of 78 mg/kg/day, which translates to a maximum intake of 54.6 mg of chlorate per day for a 70 kg person, including the 100 fold safety factor. For chlorine dioxide, the NOEL of 3.5 mg/kg/day is recommended, translating to an intake of 2.45 mg/kg/day for the 70 kg individual.

On the basis of the oxidative tendency of these oxychlorine species, to be chemically reduced by organic matter in both the produce treatment and wash waters, and subsequent municipal water treatment facilities, the levels of the three oxychlorine species are anticipated to be significantly lower than the levels calculated to be of minimal risk to individuals.

### **8.3. ENVIRONMENTAL BENEFITS.**

The use of acidified sodium chlorite/chlorous acid systems for produce disinfection offers several environmental benefits:

#### **8.3.1. NON-FORMATION OF MUTAGENS AND CARCINOGENS.**

Where ASC solutions, once approved, will often be used in place of chlorinated water in many fruit and vegetable processing operations, the potential for the formation of chlorinated organic materials in the environment will be significantly reduced<sup>11</sup>.

#### **8.3.2. REDUCTION IN AQUATIC TOXICITY.**

Where ASC solutions are used to replace chlorinated water in produce disinfection, the following adverse effects of the hypochlorite formed from chlorine will be reduced<sup>12</sup>.

- Cold water fish: 0.132 - 135 ppm (LC<sub>50</sub>-96 hr)
- Warm water fish: 0.28 - 2.1 ppm (LC<sub>50</sub>-96 hr)
- *Daphnia magna*: 0.037 - 2.1 ppm (LC<sub>50</sub>-48 hr)

These data indicate that chlorine/hypochlorite is much more toxic to both cold and warm freshwater fish than is chlorite or chlorate, and generally slightly more toxic to the *Daphnia magna* invertebrate.

## **9.0. USE OF RESOURCES AND ENERGY.**

As shown earlier in format section 6, if **as much as 25%** of the fresh market fruits and vegetables processed **in the United States were to employ ASC solutions**, at the maximum proposed use level, the amount of additional sodium chlorite consumed would be <1% of the total present consumption. Since the consumption of ASC solutions in this application will probably be significantly less than that quantity, the impact on national resources and energy by such use will be insignificant. Also no minerals will be used in the preparation or production of the subject additive. Environmental releases of chlorite, chlorate, chlorine dioxide and any of the GRAS acid activators are not expected to adversely affect threatened or endangered species nor impact historic structures.

**002150**

## **10.0. MITIGATION MEASURES.**

No adverse environmental effects are anticipated from residual "worst-case" levels of chlorine dioxide in the workplace, if this petition is approved. Therefore, no mitigation measures are required.

**002151**

## **11.0. ALTERNATIVES TO PROPOSED ACTION.**

Inasmuch as no potential adverse environmental effects are expected to occur, no mitigation alternative actions are necessary.

**002152**

**0038**



## **12.0. PREPARER.**

This Environmental Assessment was prepared by Robert D. Kross, Ph.D. of Kross-Link Laboratories. Dr. Kross has an educational background in physical chemistry, analytical chemistry and physics, and has consulted in the fields of oxychlorine chemistry, food & nutrition, biochemistry, microbiology, toxicology and environmental analysis. He was an intervenor in the siting of the Shoreham Nuclear Power Plant of the Long Island Lighting Corporation.

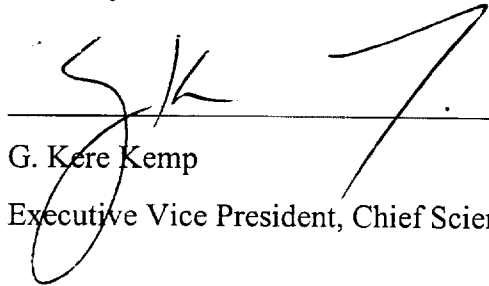
**002153**

### 13.0. CERTIFICATION.

The undersigned official certifies that the information presented is true, accurate and complete to the best knowledge of the firm.

**Date:** February 12, 1999.

**Signature:**



\_\_\_\_\_

**Name:** G. Kere Kemp

**Title:** Executive Vice President, Chief Scientific Officer

## **14.0. APPENDICES.**

### **Appendix 1. Sodium Chlorite MSDS**



A Division of Vulcan Materials Company  
P O Box 530390  
Birmingham, AL 35253-0390

# MATERIAL SAFETY DATA SHEET

24 Hour Emergency Phone 316/524-5751

## SECTION 1 PRODUCT IDENTIFICATION

CHEMICAL NAME  
Sodium Chlorite Solution

CHEMICAL FORMULA  
 $\text{NaClO}_2$

MOLECULAR WEIGHT  
90.45

### PRODUCT NAME

Technical Sodium Chlorite Solution 31.25, 31% Active Sodium Chlorite, Textone® L, Textone® XL

NOTE: This Material Safety Data Sheet is also valid for technical sodium chlorite solutions weaker than 31.25% (25% Active). Physical data, such as specific gravity will be different from the values listed.

### SYNONYMS

25% Min Active Sodium Chlorite and 38.75% Technical Sodium Chlorite

DOT IDENTIFICATION NO.  
UN 1908

## SECTION 2 COMPONENT DATA

<u>CHEMICAL NAME</u>	<u>CAS NUMBER</u>	<u>% RANGE</u>	<u>EXPOSURE STANDARDS</u>
Sodium chlorite	7758-19-2	25-34%	None Established
Sodium chloride	4647-14-5	1-6%	None Established
Sodium sulfate	7757-82-6	0-2%	None Established
Sodium chlorate	7775-09-9	0-3%	None Established
Water	7732-18-5	59-74%	None Established

## SECTION 3 PHYSICAL DATA

### APPEARANCE AND ODOR

Clear, water white to slightly  
yellow liquid, slight chlorine odor

### SPECIFIC GRAVITY

1.23-1.30 at 25/25°C

### DECOMPOSITION TEMPERATURE

175°C (347°F) (Dry material)

### BULK DENSITY

10.4-10.7 lbs./gal. at 25°C

### pH @ 25°C

> 12

### VAPOR PRESSURE @ 25°C

No Data

### SOLUBILITY IN WATER

100%

### VOLATILES, PERCENT BY VOLUME

59-74%

## SECTION 4 REACTIVITY INFORMATION

### SUMMARY OF REACTIVITY

Oxidizer

### CONDITIONS TO AVOID:

Temperatures above 175°C (347°F) (dry material)

Evaporation to dryness; dried material can ignite upon contact with combustibles.

Exposure to sunlight or ultraviolet light can reduce product strength.

002156

0042

**INCOMPATIBLE MATERIALS**

Acids, reducing agents, combustible materials, oxidizers (such as hypochlorites), sulfur-containing rubber, dirt, soap, solvents, paints.

**OTHER CONDITIONS TO AVOID**

Contamination with acids, chlorine or organic materials. Avoid contact with heat or flame source.

**HAZARDOUS DECOMPOSITION PRODUCTS**

Explosive and toxic chlorine dioxide gas will be generated on contact with acids or chlorine

**HAZARDOUS POLYMERIZATION**

Will not occur

**SECTION 5 FIRE AND EXPLOSION HAZARD INFORMATION****FLASH POINT**

Not Applicable

**AUTOIGNITION TEMPERATURE**

Not Applicable

**FLAMMABLE LIMITS IN AIR (PERCENT BY VOLUME)**

Not Applicable

**NFPA RATINGS**

Not Established for solution

**EXTINGUISHING MEDIA**

Not Applicable-Choose extinguishing media suitable for surrounding materials.

**FIRE FIGHTING TECHNIQUES AND COMMENTS**

Approach fire from upwind to avoid hazardous vapors and toxic decomposition products. Use flooding quantities of water as fog or spray. This product becomes a fire or explosion hazard if allowed to dry, so use water spray to keep fire-exposed containers cool. Extinguish fire using agent suitable for surrounding fire. See Section 7 for protective equipment for fire fighting.

**SECTION 6 TOXICOLOGY AND HEALTH INFORMATION****EXPOSURE STANDARDS**

None Established

**IMMEDIATELY DANGEROUS TO LIFE OR HEALTH:**

There is no level established for this chemical.

**ODOR THRESHOLD**

There is no data available on the odor threshold of sodium chlorite.

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE**

Deficiency in G6PD enzyme and other red blood cell diseases

**INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY**

None known or reported

**ACUTE TOXICITY****ROUTES OF EXPOSURE**

Oral, dermal, inhalation and eye contact

**INHALATION**

Inhalation may cause irritation of the mucous membranes and respiratory tract. Symptoms may include coughing, bloody nose, and sneezing. Severe overexposures may cause lung damage.

**SKIN**

Direct contact may cause severe irritation and/or burns with symptoms of redness, itching, swelling and possible destruction of tissue.

**EYE**

Mist or direct contact may cause severe irritation and possibly burns. Symptoms may include tearing, redness and in severe cases, eye damage due to burns.

002157

0043

#### INGESTION

Gastroenteritis with any or all of the following symptoms: nausea, vomiting, lethargy, diarrhea, bleeding or ulceration. Acute ingestion of large quantities may also cause anemia due to the oxidizing effects of the chemical.

#### ANIMAL TOXICOLOGY

Inhalation LC<sub>50</sub>: No available data  
Dermal LD<sub>50</sub>: > 2 g/kg (rabbit)  
Oral LD<sub>50</sub>: Approximately 350 mg/kg (rat)  
Irritation: Severe irritant with corrosive action to skin (of rabbit)  
Severe irritant to eyes (of rabbit)

#### FIRST AID

##### EYES

Immediately flush eyes with large amounts of water for at least 15 minutes while frequently lifting the upper and lower eyelids. Consult a physician immediately.

##### SKIN

Remove contaminated clothing. Immediately flush exposed skin areas with large amounts of water for at least 15 minutes. Consult a physician if burning or irritation of the skin persists. Contaminated clothing must be laundered before re-use.

##### INGESTION

DO NOT induce vomiting. Drink large quantities of water. Consult a physician immediately. DO NOT give anything by mouth if the person is unconscious or having seizures.

##### INHALATION

Move patient to fresh air and monitor for respiratory distress. If cough or difficulty in breathing develops, administer oxygen, and consult a physician immediately. In the event that breathing stops, administer artificial respiration and obtain emergency medical assistance immediately.

##### NOTES TO PHYSICIAN

Chlorine dioxide vapors are emitted when this product contacts acids or chlorine. If these vapors are inhaled, monitor patient closely for delayed development of pulmonary edema which may occur up to 48-72 hours post-inhalation.

Following ingestion, neutralization and use of activated charcoal is not indicated.

#### CHRONIC TOXICITY

##### INHALATION

There is no data available on the chronic effects of inhaling sodium chlorite.

##### SKIN

There are no studies or reports on the repeated effects of dermal exposure to sodium chlorite. Because of the acute effects, repeated direct contact may be unlikely.

##### INGESTION

The chronic ingestion of low concentrations of this product has been studied in laboratory animals. Concentrations in the drinking water of 100 ppm and higher have been shown to cause mild anemia and a minor suppression of thyroid functions in laboratory animals. All effects were reversible after cessation of treatment.

002158

Clinical studies of communities using sodium chlorite as a disinfectant found no adverse effects in the human population studied. However, other studies have suggested that those individuals deficient in an enzyme (G6PD) utilized in hemoglobin synthesis might be susceptible to the development of anemia if exposed repeatedly.

0044

#### CHRONIC TARGET ORGAN TOXICITY

Repeated exposures to solutions of chlorine dioxide at concentrations of 10-100 ppm have produced slight effects upon the thyroid in younger animals and the hematologic system. Exposures to these concentration can reduce the cellular and blood levels of glutathione, an agent which is protective against the oxidizing effect of this chemical. Exposure of laboratory animals above 100 ppm in the drinking water have shown a decrease in blood cell glutathione, red blood cell count and hemoglobin. In some studies these levels also caused a slight decrease in thyroid hormones, especially in younger animals.

#### CARCINOGENICITY

Sodium chlorite is not listed by NTP, IARC, OSHA, EPA, or any other authority as a carcinogen. Carcinogenicity studies conducted in mice and rats did not show an increase in tumors in animals exposed to sodium chlorite in their drinking water.

#### MUTAGENICITY

Sodium chlorite has been evaluated for possible mutagenic effects in several laboratory tests. Sodium chlorite tested positive in the Ames Salmonella reverse mutation assay without metabolic activators and caused chromosomal aberrations in an in vitro Chinese hamster fibroblast cell line without metabolic activators. Sodium chlorite also tested positive in the mouse micronucleus assay when administered intraperitoneally (directly into the body cavity), but was not mutagenic when administered orally. The significance of these test results for human health is unclear because the oxidizing effects of the chlorite or salting effects of sodium may significantly affect the ability of the tests to accurately detect mutagens.

#### REPRODUCTIVE TOXICITY

Sodium chlorite has not been found to be teratogenic in studies in which animals have been exposed up to 100 ppm in the drinking water. Male rats repeatedly exposed to concentrations of 100 ppm or greater in the drinking water have shown slight effects on sperm motility. No effects were observed at 10 ppm and no effects were observed on fertility rate, histology of the male reproductive system or conception rate of animals exposed at 10 ppm or higher.

#### AQUATIC TOXICITY

Sodium chlorite is slightly toxic to fish and other aquatic organisms.

For bluegill (*Lepomis macrochirus*), aquatic toxicity studies have shown a  $TL_{50}$  of 208 mg/l and  $LC_{50}$  values of 265-310 mg/l. Rainbow trout (*Salmo gairdneri*) have been tested and shown acute toxicity values of 50.6 mg/l ( $TL_{50}$ ) and 290 mg/l ( $LC_{50}$ ). Of the aquatic species tested, *Daphnia* have been the most sensitive species tested with an  $LC_{50}$  of 0.29 mg/l.

Sodium chlorite is acutely toxic to birds when administered by gavage. The acute oral  $LD_{50}$  in mallard ducks is 0.49-1.00 g/kg. In bobwhite quail the  $LD_{50}$  is 0.66 g/kg.

Sodium chlorite in the diet of birds was not acutely toxic. Eight day dietary  $LC_{50}$ 's in mallard ducks and bobwhite quail were both greater than 10,000 ppm in the diet.

## SECTION 7 PERSONAL PROTECTIVE EQUIPMENT REQUIREMENTS

### PERSONAL PROTECTION FOR ROUTINE USE OF PRODUCT

#### RESPIRATORY PROTECTION

Wear a NIOSH/MSHA approved acid gas respirator plus dust/mist pre-filters if any exposure to dust or mist is possible.

#### VENTILATION

Local exhaust ventilation is recommended if vapors, mists or aerosols are generated. Otherwise, use general exhaust ventilation.

#### SKIN AND EYE PROTECTIVE EQUIPMENT

Wear Neoprene gloves, boots, apron, chemical goggles and a face shield.

002159

0045

**OTHER**

Emergency eye wash and safety showers must be provided in the immediate work area. Thoroughly wash all contaminated clothing.

**PERSONAL PROTECTION FOR EMERGENCY SPILL AND FIRE-FIGHTING SITUATIONS**

Wear full protective clothing (chemically impermeable, full encapsulated suit) and positive pressure self-contained breathing apparatus. This product becomes a fire or explosive hazard if allowed to dry; see Section 5.

**SECTION 8 PRECAUTIONS FOR SAFE HANDLING AND STORAGE****WARNING STATEMENTS AND WARNING PROPERTIES**

HARMFUL IF SWALLOWED. MAY CAUSE IRRITATION OR BURNS TO SKIN AND EYES.  
HARMFUL TO BREATHE.

DO NOT TAKE SWALLOW OR BREATHE. AVOID CONTACT WITH SKIN, EYES AND CLOTHING.  
UPON CONTACT WITH SKIN OR EYES, WASH OFF WITH WATER.

**STORAGE CONDITIONS**

Do not store at temperatures above 100°C (212°F)  
Do not expose to direct sunlight or ultraviolet light.

**SHELF LIFE LIMITATIONS**

2 years

**INCOMPATIBLE MATERIALS FOR PACKAGING**

Combustible or readily oxidizable materials; sulfur-containing rubber

**INCOMPATIBLE MATERIALS FOR STORAGE OR TRANSPORT**

Acids, reducing agents, combustible material, oxidizers (such as hypochlorites), paints, sulfur, solvents.

**SECTION 9 SPILL AND LEAKAGE PROCEDURES**

FOR ALL TRANSPORTATION ACCIDENTS, CALL CHEMTREC AT 800-424-9300.

ALL SPILLS OR LEAKS OF THIS MATERIAL MUST BE HANDLED AND DISPOSED OF IN ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS

**REPORTABLE QUANTITY**

None listed for Sodium Chlorite Solution in 49 CFR 172.101, Appendix.

**SPILL MITIGATION PROCEDURES**

Evacuation procedures must be placed into effect. Evacuate all non-essential personnel. Hazardous concentrations in air may be found in local spill area and immediately downwind. Utilize emergency response personal protective equipment prior to the start of any response. This product may represent an explosion hazard, in the form of explosive chlorine dioxide gas if it contacts acids or chlorine. Remove all sources of ignition, such as flames, hot glowing surfaces or electric arcs. Stop source of spill as soon as possible and notify appropriate personnel.

**AIR RELEASE**

Vapors may be suppressed by the use of water fog or spray. Contain all liquids for treatment and/or disposal as a (potential) hazardous waste.

**WATER RELEASE**

Notify all downstream water users of possible contamination. Continue to handle as described in LAND SPILL, below.

002160

0046



#### LAND SPILL

Create a dike or trench to contain all liquid material. Spill materials may be absorbed using clay, soil or non-flammable commercial absorbents. Continue to keep damp. If allowed to dry, dried material can ignite in contact with combustible materials. Do not place spill materials back in their original container. Containerize and label all spill materials properly. Decontaminate all clothing and, if permitted, the spill area using strong detergent and flush with large amounts of water.

#### SPILL RESIDUES

If this product becomes a waste, it meets the criteria of a hazardous waste as defined under 40 CFR 261 and would have the following EPA hazardous waste designation: D002. Also, it will be subject to the Land Disposal Restrictions under 40 CFR 268 and must be managed accordingly.

As a hazardous liquid waste, it must be disposed of in accordance with local, state and federal regulations in a permitted hazardous waste treatment, storage and disposal facility.

### SECTION 10 TRANSPORTATION INFORMATION

This material is regulated as a DOT hazardous material.

DOT SHIPPING DESCRIPTION (49 CFR 172.101)  
CHLORITE SOLUTION, 8, UN 1908, II

PLACARD REQUIRED  
Corrosive, 1908, Class 8

The applicable packaging sections in 49 CFR are 173.202 and 173.242.

### SECTION 11 ADDITIONAL REGULATORY STATUS INFORMATION

#### TOXIC SUBSTANCES CONTROL ACT

The components of this product are listed on the Toxic Substance Control Act inventory.

#### SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT (SARA) TITLE III HAZARD CATEGORIES (40 CFR 370.2)

HEALTH: Immediate (Acute), Delayed (Chronic)

PHYSICAL: Fire

#### EMERGENCY PLANNING AND COMMUNITY RIGHT TO KNOW (40 CFR 355, APP.A)

E H S-THRESHOLD PLANNING QUANTITY  
None Established

SUPPLIER NOTIFICATION REQUIREMENTS, PER 40 CFR 372.45:  
None Established

#### Medical Emergencies:

Call collect 24 hours a day  
for emergency toxicological  
information 415/821-3182

#### Other Emergency information:

Call 316/524-5751 (24 Hours)

#### For any other information contact:

Vulcan Chemicals  
Technical and Environmental Services  
P O Box 530390  
Birmingham, AL 35253-0390  
800/873-4898  
8 AM - 5 PM, Central Time  
Monday through Friday

NOTICE: Vulcan Chemicals believes that the information contained on this material safety data sheet is accurate. The suggested procedures are based on experience as of the date of publication. They are not necessarily all-inclusive nor fully adequate in every circumstance. Also, the suggestions should not be confused with nor followed in violation of applicable laws, regulation, rules or insurance requirements.

NO WARRANTY IS MADE, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

Date of Preparation: June 1, 1995

FORM 3239-640

002161

0047

## 15.0 BIBLIOGRAPHY

1. Data obtained from U.S. Department of Agriculture, Agricultural Statistic Board, National Agricultural Statistics Service, Statistical Bulletins 899 *et seq.*; available from the Internet on, for example, <http://usda.mannlib.cornell.edu/data-sets/specialty/95900/sb900.txt>
2. Masschelein, W.J. and R.G. Rice (1979). Chlorine Dioxide, Chemistry and Environmental Impact of Oxychlorine Compounds. Ann Arbor Science Publishers Inc. pages 22-3.
3. Wetzel, E.D. and Murphy, S.B. "Interferences at Publicly Owned Treatment Works," NTIS Report No. PB90-108853.
4. "Guidance Manual for Preventing Interference at POTWs, USEPA, Sept., 1987. NTIS Report No. PB92-117969.
5. Bianchine JR, Lubbers JR, Chauhan S. (1980), "The safety study of chlorine dioxide and its metabolites in man." Summary Report. Grant No. 805643. Submitted to the U.S. Environmental Protection Agency, Cincinnati, Ohio.
6. Lubbers JR, Chauhan S, & Bianchine JR (1981). Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Fund Appl Toxicol 1:334-338.
7. Lubbers JR, Chauhan S, & Bianchine JR (1982). Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Environ Health Perspec 46:57-62.
8. Lubbers JR, Bianchine JR, & Bull RJ (1983). Safety of oral chlorine dioxide, chlorite, and chlorate ingestion in man. In: Jolley RL *et al.* (eds.), "Water Chlorination: Environmental Impact and Health Effects," Vol. 4, book 2. Ann Arbor, Mich., Ann Arbor Science, 1983, pp. 1335-1341.
9. Lubbers JR & Bianchine JR (1984). Effects of the acute rising dose administration of chlorine dioxide, chlorate and chlorite to normal healthy adult male volunteers. J Environ Pathol Toxicol Oncol 5(4/5):215-228.
10. CHLORINE DIOXIDE-DRINKING WATER ISSUES; Second International Symposium, May 7,8, 1992, Chemical Manufacturers Association/American Water Works Association-Research Foundation/ United States Environmental Protection Agency, pages 177-181.
11. See U.S.EPA's "Proposed Rule for Disinfectants and Disinfectant By-Products: 58 Fed. Reg. pgs. 38668-38829, July 29, 1994.
12. Reregistration Eligibility Document for Sodium and Calcium Hypochlorite Salts, February 1992. NTIS Report No. 540/RD-92-193.

002162